K 121269

TEVA Medical Ltd

migada

510(k) Summary:

JAN 2 2 2013

Company Name:

Migada Plant

Contact Person:

Ido Kanyon
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US Agent:

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Date prepared: April 15, 2012 (revised on December, 2012)

Trade Name: I.V. Administration Set

Common/usual name: I.V. administration set

Classification name: Set, Administration, Intravascular

Product Code: FPA

Regulation No.: 880.5440

Class: II

Panel identification: General Hospital Panel

Description of the device:

The I.V. Administration Set is single use, sterile, non-pyrogenic device used to administer intravenous solutions and/or drugs solutions from a container to a patient's vascular system. This device is not made with natural rubber latex.
The I.V Administration set is comprised of various generic components which are broadly used through the industry such as: Spike, drip chamber, Y-site, tubing, flow regulator, clamp, needless injection site and luer connection. The set may include two unique components:

1. Spike: The Spike is intended for connection to the spike port of an infusion bag. In cases when a drug needs to be introduced, a septum enables connection to the Tevadaptor™ Syringe Adaptor for withdrawal of diluents or introduction of drug.
2. ULTRASITE™ Injection site (cleared under 510(k) No. K031923). The Ultrasite Valve is a needle-free, cap less positive displacement valve to be use in place of needles for the administration of fluids. The ULTRASITE™ Valve may be accessed with standard male luer connectors and requires no special accessories devices. The Ultrasite device eliminates the use of needles to access the set during IV administration and aids in the prevention of needle stick injuries.

Teva Medical Migada Plant offers both standard and custom sets with tubing of various lengths to meet customer requirements and specifications.

Intended Use:

The I.V. Administration Set is a single use, sterile I.V. set for administration of drugs and/ or fluids from a container to a patient vascular system.

Conclusion -
The evaluation of the I.V. Administration Set does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate devices.

Teva Medical Ltd. Migada Plant - Industrial Zone Kiryat Shmona, ISRAEL, Tel: +972-4-6908800

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 22, 2013

Mr. Ido Kanyon
Manager, Quality Assurance and Regulatory Affairs
Migada Plant
North Industrial Zone
Kiryat Shmona, Israel 10258

Re: K121269
Trade/Device Name: I.V. Administration Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: December 6, 2012
Received: December 13, 2012

Dear Mr. Kanyon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TEVA Medical Ltd

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INDICATIONS FOR USE

510(k) Number (if known): K121269

Device Name: I.V. Administration Set

Indications for Use: The I.V. Administration Set is a single use, sterile I.V. set for administration of drugs and/ or fluids from a container to a patient vascular system.

Prescription Use ___X___ OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE):

Digitally signed by Richard C. Chapman
Date: 2013.01.22 14:09:12 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K121269

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